DETAILED ACTION

Applicant's argument filed on 6/1/2010 is acknowledged. Claims 2, 4, 8, and 9 are cancelled. Claims 1, 3, 5-7, and 10 are pending. Claim 10 is withdrawn. **Claims 1, 3, and 5-7 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 7 recites "The kit according to claim 1 for use as a medicament" in line 1. However, claim 1 is a kit for the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatis, osteoporosis and asthma in humans or tail and mane eczema in horse, thus claim 1 is a medicament itself, and claim 7 does not further limit claim 1.

It is noted that Applicant is suggested to recite "a kit for the treatment of lupus…comprising.." instead of "a kit for use in the treatment of lupus...comprising...", so as to distinguish from the "use of" claims that are not allowable.

Claim Rejection 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 5-7 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating lupus in humans or tail and mane eczema in horses, does not reasonably provide enablement for treating multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the predictability or unpredictability of the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is drawn to a kit for use in the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma in humans or tail and mane eczema in horses comprising: a first composition including a unit dose of 100 -

1000 mg parts of *Melissa officinalis;* a second composition including a unit dose of 100 -1000 mg parts of *Eleutherococcus senticosus;* a third composition including a unit dose of 100 -1000 m~ parts of *Avena sativa;* a fourth composition including a unit dose of 100 –1000 mg parts of *Ballota nigra;* a fifth composition including a unit dose of 100-1000 mg roots of *Glycyrrhiza glabra/gan cao;* and a sixth composition including a unit dose of 100 -1000 m~ roots of *Uncaria tomentosa.*

Since the kit is drawn to the treatment of five different diseases, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma that Applicant is not enabled for, the Examiner is going to use the treatment of multiple sclerosis as an example to explain Applicants' enablement issue.

According to Merck Manual (Multiple Sclerosis from Merck Manual, accessed on 7/15/2010, pp. 1-6), in multiple sclerosis, patches of myelin and underlying nerve fibers in the eyes, brain, and spinal cord are damaged or destroyed.

- The cause is unknown but may involve an attack by the immune system against the body's own tissues (autoimmune reaction).
- Usually, periods of relatively good health alternate with episodes of worsening symptoms.
- People may have vision problems and abnormal sensations, and movements may be weak and clumsy.
- Usually, doctors base the diagnosis on symptoms and results of a physical examination and magnetic resonance imaging (MRI).

- Treatment includes corticosteroids, drugs that help keep the immune system from attacking the body, and drugs to relieve symptoms.
- Often, the disorder slowly worsens, disabling some people, but life span is unaffected unless the disorder is very severe.

The term "multiple sclerosis" refers to the many areas of scarring (sclerosis) that result from destruction of the tissues that wrap around nerves (myelin sheath). This destruction is called demyelination. Sometimes the nerve fibers that send messages (axons) are also damaged. Over time, the brain may shrink in size because axons are destroyed.

In the United States, about 400,000 people, mostly young adults, have multiple sclerosis. Most commonly, it begins between the ages of 20 and 40. It is more common among women. Most people have periods of relatively good health (remissions) alternating with periods of worsening symptoms (flare-ups or relapses). Relapses can be mild or debilitating. Recovery during remission is good but incomplete. Thus, the disorder worsens slowly over time.

(2) the breadth of the claims:

Several subtypes, or patterns of progression, have been described. Subtypes use the past course of the disease in an attempt to predict the future course. They are important not only for prognosis but also for therapeutic decisions. In 1996 the United States National Multiple Sclerosis Society standardized four subtype definitions (Lublin et al, Defining the clinical course of multiple sclerosis: results of an international survey. National Multiple Sclerosis Society (USA) Advisory Committee on Clinical Trials of New Agents in Multiple Sclerosis, Neurology. 1996 46(4): 907-11).

1. relapsing remitting,

2. secondary progressive,

3. primary progressive, and

4. progressive relapsing.

The relapsing-remitting subtype is characterized by unpredictable relapses followed by periods of months to years of relative quiet (remission) with no new signs of disease activity. Deficits suffered during attacks may either resolve or leave sequelae, the latter being more common as a function of time. This describes the initial course of 85–90% of individuals with MS. When deficits always resolve between attacks, this is sometimes referred to as benign *MS*, although patients will still accrue some degree of disability in the long term. The relapsing-remitting subtype usually begins with a clinically isolated syndrome (CIS). In CIS, a patient has an attack suggestive of demyelination, but does not fulfill the criteria for multiple sclerosis. However only 30 to 70% of persons experiencing CIS later develop MS.

Secondary progressive MS (sometimes called "galloping MS") describes around 65 % of those with an initial relapsing-remitting MS, who then begin to have progressive neurologic decline between acute attacks without any definite periods of remission. Occasional relapses and minor remissions may appear. The median time between disease onset and conversion from relapsing-remitting to secondary progressive MS is 19 years.

The primary progressive subtype describes the approximately 10–15% of individuals who never have remission after their initial MS symptoms. It is characterized by progression of

disability from onset, with no, or only occasional and minor, remissions and improvements. The age of onset for the primary progressive subtype is later than for the relapsing-remitting, but similar to mean age of progression between the relapsing-remitting and the secondary progressive. In both cases it is around 40 years of age.

Progressive relapsing MS describes those individuals who, from onset, have a steady neurologic decline but also suffer clear superimposed attacks. This is the least common of all subtypes. Atypical variants of MS with non-standard behavior have been described. These include Devic's disease, Balo concentric sclerosis, Schilder's diffuse sclerosis and Marburg multiple sclerosis; and there is debate on whether they are MS variants or different diseases. Multiple sclerosis also behaves differently in children, taking more time to reach the progressive stage. Nevertheless they still reach it at a lower mean age than adults.

Therefore, the breadth of the claims encompasses by administering to a subject the claimed kit, all types of MS could be treated.

(3) the state of the art:

Peizhong et al (Peizhong et al, Is multiple sclerosis a mitochondrial disease? Biochimica et biophysica acta, (2010 Jan) Vol. 1802, No. 1, pp. 66-79) teach multiple sclerosis (MS) is a relatively common and etiologically unknown disease with no cure. It is the leading cause of neurological disability in young adults, affecting over two million people worldwide. Traditionally, MS has been considered a chronic, inflammatory disorder of the central white matter in which ensuing demyelination results in physical disability. Recently, MS has become increasingly viewed as a neurodegenerative disorder in which axonal injury, neuronal loss, and

atrophy of the central nervous system leads to permanent neurological and clinical disability (see Abstract).

Hans-Peter (Hans-Peter, High-dose, high-frequency recombinant interferon beta-1a in the treatment of multiple sclerosis, Expert opinion on pharmacotherapy, (2009 Feb) Vol. 10, No. 2, pp. 291-309) teaches there is at present no cure for multiple sclerosis (MS), and existing therapies are designed primarily to prevent lesion formation, decrease the rate and severity of relapses and delay the resulting disability by reducing levels of inflammation (see Abstract).

Fiske et al (Fiske et al, Multiple sclerosis and oral care, Dental update, (2002 Jul-Aug) Vol. 29, No. 6, pp. 273-83) teach multiple sclerosis is a complex neurological condition affecting sensory and motor nerve transmission. Its progression and symptoms are unpredictable and vary from person to person as well as over time. Common early symptoms include visual disturbances, facial pain or trigeminal neuralgia and paraesthesia or numbness of feet, legs, hands and arms. These, plus symptoms of spasticity, spasms, tremor, fatigue, depression and progressive disability, impact on the individual's ability to maintain oral health, cope with dental treatment and access dental services. Also, many of the medications used in the symptomatic management of the condition have the potential to cause dry mouth and associated oral disease. There is no cure for multiple sclerosis, and treatment focuses on prevention of disability and maintenance of quality of life (see Abstract).

Holland et al (Holland et al, Adherence to disease-modifying therapy in multiple sclerosis: Part II, Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses, (2001 Nov-Dec) Vol. 26, No. 6, pp. 221-6) teach multiple sclerosis (MS) is a chronic, debilitating disease for which there is no cure; however, the recent introduction of injectable

immunomodulating agents has reduced the rate of relapsing episodes and possibly slowed the progression of the disease. Since MS has an unpredictable course, and treatments can produce side effects, adherence to the recommended therapy is a complex and challenging issue (see Abstract).

Therefore, multiple sclerosis (MS) is an unknown disease with no cure, and it leads to permanent neurological and clinical disability. Also prior art teaches that MS has an unpredictable course, and treatments can produce side effects.

(4) the relative skill of those in the art

The relative skill in the art is high. The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g.M.D., Ph.D., Pharm. D. or combinations thereof).

(5) The predictability or unpredictability of the art:

Treating MS is unpredictable in the art. For instance, Steinman et al (Steinman et al, How to successfully apply animal studies in experimental allergic encephalomyelitis to research on multiple sclerosis, Ann Neurol 2006; 60: 12-21) teach that "MS (multiple sclerosis) is a complicated disease, the cause and the pathogenesis of which are incompletely understood…Whether MS is actually a single disease or whether it is a primarily or initially an 'immune disease,' 'an infectious disease,' 'an inflammatory disease,' or a 'degenerative disease,' or a combination of all these types are all question with answers that are currently unknown" (see p. 12). Sriram et al (Sriram et al, Experimental allergic encephalomyeliits: a misleading model of multiple sclerosis, Ann Neurol 2005; 58: 939-945) state that the "[a]lthough the cause and

pathogenesis of multiple sclerosis (MS) are unknown, current prevailing hypothesis favors MS to represent an autoimmune disorder directed against the nervous system antigen. The basic concept poses that exposure to environmental pathogens activates the autoreactive T cells that recognize the central nervous system (CNS) antoantigens, leasing to inflammation and demyelination. This belief is promoted by some similarities between MS and various animal models of experimental allergic encephalitis (EAE)" (see p. 939). Even though the art recognizes EAE as a model of MS, Sriram et al states that "EAE is a disorder that differs immunogenically and pathologically between species, according, in part, to the type of antigen used to induce it and the species in which the model is tested. None of the EAE models represents MS and they therefore are imprecise methods to elucidate either the pathogenesis or to develop therapeutic strategies in MS" (see p. 943).

(6) The amount of direction or guidance presented.

The specification has not provided guidance on the treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human.

(7) The presence or absence of working examples.

There is no working example regarding the treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human.

(8) The quantity of experimentation necessary:

Since treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma is such a complex issue, the state of the art has not been able to treat the above mentioned disease using the claimed kit, and the specification has not provided any guidance regarding the

treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma, the quantity of experimentation is undue, and one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine if the claimed kit would be effective in the treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma.

Based on the aforementioned reasons the Examiner concludes that the specification, while being enabling for treating lupus in humans or tail and mane eczema in horses, does not reasonably provide enablement for treating multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human without requiring the ordinary skilled artisan to undertake undue experimentation. Since the state of the art is highly unpredictable and requires much greater guidance for an ordinary skilled artisan to effectively treating multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human, burdensome experimentation, such as clinical studies would necessarily be required of the ordinary skilled artisan to establish the treatment of multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis and asthma in human.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Qiuwen Mi/

Examiner, Art Unit 1655